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OFFICIAL*SC 1/29/98*

Date January 29, 1998

To Examiner Stephen Gucker
Patent and Trademark Office

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From John W. Freeman

Re Applicant: Staurt A. Lipton Art Unit: 1812
Serial No.: 08/346,910 Examiner: S. Gucker
Filed: November 30, 1994
Title: PROTEIN 68075 AND ITS USE FOR REGENERATING NERVE
CELL PROCESSES

**Number of pages
including this page** 7

Message Attached is a copy of the petition to withdraw finality and amendment remarks responsive to September 4, 1996 office action filed September 3, 1997.

**PLEASE CALL EXAMINER GUCKER IMMEDIATELY
AT 308-6571 TO PICK UP THIS FAX**

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#15/Amendt ²⁰⁰²
Gordon 01/30/98

PATENT

ATTORNEY DOCKET NO. 08262/017004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Stuart A. Lipton
 Serial No.: 08/346,910
 Filed : November 30, 1994
 Title : PROTEIN 68075 AND ITS USE FOR REGENERATING NERVE CELL PROCESSES

Art Unit: 1812
 Examiner: Gucker, S.

Box AF

Assistant Commissioner for Patents
 Washington, DC 20231

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Pa. 385.00
OWE \$1000

PETITION TO WITHDRAW FINALITY AND AMENDMENT/REMARKS
RESPONSIVE TO SEPTEMBER 4, 1996 OFFICE ACTION.

Pursuant to 37 CFR §1.129(a), please withdraw the finality of the rejections in the office action mailed September 4, 1996. Applicants note that this application had been pending for more than two years as of June 8, 1995, taking into account references to earlier filed applications under 35 U.S.C. §120. This Petition is filed while the application is still pending and before the filing of a brief. Applicants enclose a check in the amount of \$335.00, pursuant to 37 CFR §1.17(r). No previous request to remove finality under this section has been filed.

FEE VALUE ACCOUNT APPLY	
DEPOSIT ACCOUNT NO	
06	1050
FEE CODE	VALUE FORWARDED
296	335.00

Dr.
\$10

Please consider the following amendment and remarks responsive to the March 4, 1997 office action.

AMENDMENT

Please amend claim 8 in line 2 by changing "94525" to -

-97525--.

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Date of Deposit

September 3, 1997
 I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

[Signature]

OFFICIALREMARKS

Responsive to the office action mailed September 4, 1996 (paper 11), please consider the following remarks. Claims 8-10 are the only claims pending in this case.

The following remarks address each paragraph of paper 11.

Section 112, paragraph 1

Claim 8 is drawn to a specific cDNA (clone TR2B) which has been deposited with the American Type Culture Collection. Claim 9 is drawn to nucleic acid that hybridizes with TR2B under stringent conditions and enhances a neuroregenerative process. Claim 10 is drawn to fragments of clone TR2B that enhance a neuroregenerative process.

The examiner agrees that the deposit of clone TR2B was made in the form of a vector well known in the art, λ gt11, having the clone ligated therein. The rejection is based on the examiner's conclusion that those skilled in the art could not use the invention once they obtain the deposit. The examiner agrees that the skilled artisan could excise the claimed cDNA from the plasmid using the restriction enzyme EcoRI, but the examiner maintains that (paper 11, page 3, lines 6-9),

"...in order to use the claimed nucleic acid, the sequence of the nucleic acid must be known (described) or antibodies that can detect the protein it expresses must be publicly available..."

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In fact, it is a simple matter for the art to obtain the expression product without knowing the cDNA sequence or having protein-specific antibodies. Those skilled in the art are well aware of off-the-shelf kits, such as the GEX/GES fusion expression kits sold by Pharmacia. Those kits are made precisely for the purpose of isolating the expression product of a specific uncharacterized DNA. According to those kits, the DNA is ligated to DNA encoding glutathione S-transferase (GST), positioned for high level expression by an *E. coli* tac promoter. The resulting fusion is expressed and recovered using Glutathione Sepharose 4B column. The fusion binds to the column to separate it from most impurities. The fusion is then eluted from the column and cleaved under mild conditions which enable easy recovery of the expression product with no residue from the GST. See, for example, Smith et al. *Gene* 67:31 (1988) and John et al. *Nature* 338:585 (1989).

Attentively other systems, such as β -galactosidase fusions can readily identify clones expressing the fusion and they can permit recovery of the fusion.

In short, recovery of the expression product in the absence of sequence information or antibody is far from an insurmountable problem. It has been routine since at least as early as applicant's filing date.

Quite apart from the use of fusions as described above, the sequencing of a given isolated DNA segment is routine. It is long past time for the U.S. Patent and Trademark Office to recognize this fact.

One skilled in the art at the time this application was filed would be able to obtain the protein expression product of the claimed DNA clones, without undue experimentation, using techniques that are routine. In short, the premise for the §112 ¶1 rejection is wrong. The skilled artisan would need neither an antibody nor sequence to use the claimed nucleic acid.

The examiner cites page 5, lines 23-25 of the specification, which says that Applicant has found that the protein encoded by the claimed DNA "...enhances the regeneration of nerve cell processes in vivo in humans." The applicant has conceived of and enabled a human therapy. The applicant does not claim to have done experiments on human beings. The basis of applicant's finding is clearly the animal experiments such as those taught in the specification.

The fact that still further work was conceived or accomplished after the filing is not the issue. The issue is whether those in the art using ordinary skill could obtain and use the claimed DNA based on the deposit and information provided in the specification. Clearly, simple fusion/expression technology would enable the art to obtain the encoded protein without undue experimentation.

Section 112, paragraph 2

The examiner's attention to the typographical error in claim 8 is appreciated, and the amendment corrects that error.


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Conclusion

If there are any other charges, or any credits, please apply them to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 9/3/97


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